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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:	
HANS-ULRICH PETEREIT, ET AL.	:	EXAMINER: BERNSHTEYN, MICHAEL
SERIAL NO: 10/510,371	:	
FILED: OCTOBER 5, 2004	:	GROUP ART UNIT: 1713
FOR: PH-SENSITIVE POLYMER	:	

REPLY BRIEF

MAIL STOP APPEAL BRIEF-PATENTS
COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

The following is a Reply to the arguments presented in the Examiner's Answer dated September 14, 2007. The Appellants refer to their arguments in the Appeal Brief and respond to the arguments in section (10) of the Examiner's Answer below.

Response to Arguments in Examiner's Answer

1. Anticipation and Obviousness. The remaining rejection is an obviousness rejection based on Haddleton, who discloses preparing polymer emulsions for various applications by a method (free-radical polymerization using transition metal catalyst complexes) which introduces transition metals into the resulting polymers; in view of Rehmer, who teaches making copolymers for pressure sensitive adhesives using an emulsion polymerization method which also contemplates use of polyvalent metal ions as well as other types of reducing agents (col. 3, lines 23-24). Neither document suggests making a pH-sensitive polymer that does not contain transition metal complexes and that is substantially non-toxic (i.e., less than 5% haemolysis of red blood cells at pH 7.4). While numerous different types of polymers may be produced for various applications—some toxic, some non-toxic, some pH-sensitive, some pH-insensitive--neither document provides a reasonable

expectation of success for producing a pH-sensitive polymer having particular biological properties required by independent claim 1.

2. Citing In re Boesch and Sianey, 205 USPQ 215 (CCPA 1980), the Examiner asserts that it would have been obvious to optimize the prior art copolymer formulations. However, the Examiner's Answer does not indicate which property of the prior art polymers should be optimized or point out where the prior art says that these properties should be optimized

Assuming, *arguendo*, that the prior art suggested the desirability of producing polymers that are non-toxic (i.e., no transition metal complexes) in biological applications, it provides no guidance as to how to optimize these properties, nor does it suggest that reducing transition metal complex content would optimize the non-toxic biological properties of such copolymers. Similarly, there is no suggestion to optimize the chemical formulation of a copolymer to obtain the specific biological properties required by claim 1 ("brings about at least 60% haemolysis at pH 5.5, and less than 5% haemolysis a pH 7.4"). "A particular parameter must be recognized as a results-effective variable. . .before the determination of an optimum or workable ranges of said variable might be characterized as routine experimentation", *In re Antonie*, 195 USPQ 6 (CCPA 1977); MPEP 2144.05(II)(B). Here the Examiner has not shown that minimizing transition metal content of a copolymer was a recognized results-effective variable for producing the claimed pH-sensitive polymer.

3. Page 9, last paragraph, of the Examiner's Answer properly identifies claim 1 as a product claim, but asserts that any process limitations are not material. The claimed pH-sensitive polymer of claim 1 is deemed to be substantially the same as that of Haddleton and Rehmer. Initially, there are no process limitations in claim 1. Claim 1 requires a pH-sensitive polymer that does not contain transition metal complexes. Haddleton teaches a method which would produce aqueous polymers containing transition metal complexes. While Rehmer contemplates polymers produced using emulsion polymerization which may also include transition metals, it does not suggest producing the pH-sensitive polymers of claim 1, nor specifically suggest omitting transition metals. Rehmer is unconcerned with whether a polymer has the properties required by claim 1, because it is directed to making adhesives. Haddleton also is silent about polymers having the functional properties required by claim 1.

4. Page 10, first paragraph, of the Examiner's Answer considers that "the focal argument resides in the contention that there is no motivation for selecting polymers which brings about at least 60% haemolysis at pH 5.5 and less than 5% haemolysis of human red blood cells at pH 7.4". *In re Spada*, 15 USPQ2d 1965 (Fed. Cir. 1990) is cited as indicating that products which are not novel are not rendered novel by recitation of their inherent properties.

As noted by the Examiner's Answer, the rejection on appeal is an obviousness rejection, not an anticipation (lack of novelty) rejection. *In re Spada* concerns an anticipation rejection and the functional properties required by claim 1 are not inherent to the transition metal complex free polymers allegedly suggested by the prior art.

With regard to the issue of obviousness, the prior art provides no suggestion or expectation of success for obtaining a transition metal complex free polymer having the functional properties required by claim 1. These properties are not inherent to polymers produced by the prior art methods as demonstrated by the Appellants. Some polymers, such as that of Polymer S-100 (see page 12, line 7 of the Supplemental Appeal Brief), do not have this functional property. There is no suggestion in the prior art to produce polymers having these properties, or even that polymers having these functional properties can be produced using the prior art methods. This limitation must be addressed for purposes of obviousness, since not all the polymers produced by using emulsion polymerization of Rehmer in conjunction with the process of Haddleton would inherently have these properties; MPEP 2143.03.

In re Best, 195 USPQ 430 (CCPA 1977) is cited to assert that the Appellants must prove that the prior art polymers have different properties than what is claimed. *In re Best* is directed to an anticipation rejection where a functional limitation is critical for establishing novelty of a product and indicates:

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require the Applicant to prove that the prior art products **do not necessarily or inherently possess the characteristics of his claimed product**.

The Appellants have shown that the genus of polymers that could be produced by the combination of prior art methods does **not necessarily or inherently possess the characteristics** of the polymer of claim 1. Not all polymers produced by prior art methods

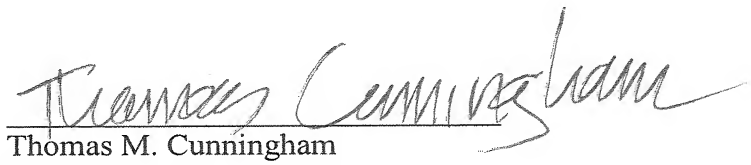
have these properties as evidenced by Polymer S-100. Moreover, the prior art provides no motivation for producing the pH-sensitive polymers having the functional properties required by claim 1 both with regard to (i) omitting toxic transition metal complexes and with respect to (ii) the specific pH-sensitive properties required by the last clause in claim 1.

RELIEF REQUESTED

In view of their remarks in the Appeal Brief and those above, the Appellants respectfully request that the ground of rejection above be REVERSED.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



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